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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SWEET, THOMAS

ART UNIT PAPER NUMBER

3738

DATE MAILED: 02/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/067,722

Applicant(s)

GERBERDING, BRENT C.

Examiner

Thomas J Sweet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-29, 31 and 33-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35-40 is/are allowed.
- 6) ☒ Claim(s) 1-19 and 41-47 is/are rejected.
- 7) ☒ Claim(s) 20-29, 31, 33 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “separation portions being configured to separate under different conditions” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. The Examiner suggests a series of figures demonstrating the progression of the portions separating.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 20-29, 31 and 33-34 are objected to because of the following informalities: Claims 20-29, 31 and 33-34 rely on a feature no shown in the drawings as discussed above. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 15-19, 41-45 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Sgro (US 606312). Sgro discloses medical device (fig. 1) comprising a catheter

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(3), an expandable balloon (4), an expandable endoprosthesis (stent, 5) positioned on the balloon and an expandable sleeve (6) extending over an end of the endoprosthesis and a portion of the balloon adjacent the endoprosthesis wherein the sleeve is configured to separate (9) into a plurality of detached portions (6a, 6 and 6b) along separation portions extending along a portion of the circumference of the sleeve and once detached the sleeve has a surface on each end defining an opening.

Regarding claims 6-8, the catheter comprising a balloon comprises tapered (sleeve) portions (4a and 4b) and the sleeve attaches to these portions (balloon and catheter).

Regarding claims 11-12, Column 5, lines 5-10.

Regarding claim 15, the sleeve is perforated defining lateral openings.

Regarding claims 16-17, the sleeve inherently is configured to separate at a predetermined level of balloon expansion, which would be smaller, then the diameter of the vessel. Otherwise the stent could not be left in the vessel. There is also a pressure associated with this predetermined expansion and thereby controlled by the physician using pump (7) with a pressure gauge.

Regarding claim 19, in the undeployed configuration the endoprosthesis is embedded (surrounded) in the sleeve.

Regarding claim 43, may be a self-expanding prosthesis (col 5, line 14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sgro in view of Bigus et al. Sgro discloses a medical device as discussed above. However, Sgro remains silent as to whether the sleeve comprises a therapeutic agent. It is well known in the art of endoprosthesis delivery systems to include medicament on or in a deployment sleeve for the purpose of treating the area of implantation as for example taught by Bigus et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include medicament in or on the sleeve of Sgro, because it is well known in the art to do so to treat the implanted area.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sgro. Sgro discloses a medical device as discussed above. Sgro remains silent as to whether the medical device includes a sheath over the sleeve. It is well known in the art of endoprosthesis delivery systems to include sheath over a sleeve for the purpose of protecting the sleeve and help guide the catheter during the insertion procedure. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include sheath over a sleeve of Sgro, because it is well known in the art to do so to protecting the sleeve and help guide the catheter during the insertion procedure.

Response to Arguments

Applicant's arguments with respect to claims 1 and 41 have been considered but are moot in view of the new ground(s) of rejection.

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Allowable Subject Matter

Claims 35-40 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J Sweet whose telephone number is (703) 308-4018.

The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tjs



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